K133335

BARD
ACCESS SYSTEMS

FEB 14 2014

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Amy Honey Regulatory Affairs Specialist
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	Date of Preparation:	October 15, 2013
Subject Device	Trade Name:	Power and Non Power-Injectable Implantable Ports with Groshong® Catheter
	Common Name:	Implanted Infusion Port & Catheter
	Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Product Code:	LJT
	Regulation:	21 CFR §880.5965
Predicate Devices	Trade Name:	PowerPort® Implantable Port with Groshong® Catheter
	Common Name:	Implanted Infusion Port & Catheter
	Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Product Code:	LJT
	Regulation:	21 CFR §880.5965
	Premarket Notification:	K081311
	Trade Name:	PowerPort® Polymeric Port with 8 F Single Lumen ChronoFlex® Catheter
	Common Name:	Implanted Infusion Port & Catheter
	Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Product Code:	LJT
	Regulation:	21 CFR §880.5965
	Premarket Notification:	K063377

Trade Name:	BardPort® Titanium Ports
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K050310

Trade Name:	X-Port® Duo Port
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K032044

Trade Name:	BardPort® X-Port® *isp* Port
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K022983

Trade Name:	Plastic Low-Profile Subcutaneous Port
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K924250

Trade Name:	Plastic Attachable Dual Port
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K912702

Trade Name:	Cath-Tech Port Implantable Vascular Access System
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K880571

Trade Name:	Hickman Plastic Subcutaneous Port
Common Name:	Implanted Infusion Port & Catheter
Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Product Code:	LJT
Regulation:	21 CFR §880.5965
Premarket Notification:	K873213

Device Description

PowerPort®

PowerPort® Implantable Ports are designed to provide repeated access to the vascular system without the need for repeated venipuncture or daily care of an external catheter. Long-Term Implantable Ports consist of a rigid housing and a self-sealing septum. The catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters. Groshong® catheters are attached to the port by the physician during implantation.

PowerPort® Implantable Ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort® ports must be accessed with a Bard PowerLoc® Safety Infusion Set (SIS) to create a power-injectable system.

Non Power-Injectable Ports

Long-Term Implantable Ports are designed to provide repeated access to the vascular system without the need for repeated venipuncture or daily care of an external catheter. Long-Term Implantable Ports consist of a rigid housing and a self-sealing septum. The catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters. Groshong® catheters are attached to the port by the physician during implantation.

Long-Term Implantable Ports can be used for routine vascular access using a non-coring access needle.

Intended Use	Power and Non Power-Injectable Implantable Ports are intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.
Indications For Use	PowerPort® The PowerPort® Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc® Brand Safety Infusion Set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s. Non Power-Injectable Ports The BardPort®, SlimPort®, and X-Port® implantable ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.
Technological Characteristics	There have been no changes to the technological characteristics or design of the Power and Non Power-Injectable Implantable Ports with Groshong® Catheter; therefore, they are substantially equivalent with respect to basic design and function of the of the predicate devices. Extending the maintenance protocol from a four-week flushing period to a 90-day flushing period does not impact the intended use, and has been shown through clinical data not to raise any new questions regarding safety or efficacy.
Safety & Performance Tests: Non-Clinical	Verification and validation testing were not required for this submission. Safety and efficacy of the change was supported through clinical data; no physical testing was required. User requirements and use-related risks have been evaluated in and mitigated through a clinical study, as well as in the Instructions for Use.

Safety & Performance Tests: Clinical	Bard currently recommends that Power and Non Power-Injectable Implantable Ports with Groshong® Catheter be filled with normal saline after each use, and if the port remains unused for long periods of time, the saline lock should be changed by flushing at least every four weeks. Under Institutional Review Board oversight, clinical data were independently collected from patients at five major oncology centers to provide clinical evidence in support of extending the maximum recommended maintenance flushing interval to at least every 90 days for Bard ports with distally-valved (Groshong®) catheters. The study was conducted at five sites in the United States. Study subjects consisted of post-infusional adult males or females ≥ 21 years of age that had a Bard port implanted. The primary endpoint was to compare the rate of adverse events at three time points in Group A versus extended accession intervals in Group B and Group C. Considering solely the saline-only intervals, the study demonstrated that approximately 57% of the collected patient-day data represented flushing with saline only. Overall, there were 465 saline-only intervals recorded with 28,452 patient-days of follow-up. Only one adverse event was recorded in the saline-only group, yielding an incidence rate of 0.35 adverse events per 10,000 patient-days, with a 95% Poisson confidence interval (0.01, 1.96). Maintenance flushing of Groshong® port systems has been shown to be safe for a wide variety of time intervals based on the very low adverse event rates noted in the clinical data. An extension of the maintenance flushing schedule from its current label of every four weeks to every 90 days with saline only is recommended.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Power and Non Power-Injectable Implantable Ports with Groshong® Catheter met the minimum requirements for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation, and indications for use to the predicate devices cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Bard Access Systems, Incorporated
Ms. Amy Honey
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K133335
Trade/Device Name: PowerPort®, Non Power-Injectable Ports
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: II
Product Code: LJT
Dated: October 18, 2013
Received: October 29, 2014

Dear Ms. Honey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133335

Device Name: PowerPort®

Indications for Use:

The PowerPort® Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with a PowerLoc® safety infusion set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Device Name: Non Power-Injectable Ports

Indications for Use:

The BardPort®, SlimPort®, and X-Port® implantable ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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